

## **REMARKS**

Claims 1-37 are presently pending in the case. Claims 6 and 17 have been withdrawn from consideration.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 1-16 and 18-37 under 35 USC 103(a) as being unpatentable over U.S. Patent 5,647,349 to Ohki et al (hereinafter Ohki et al) in view of U.S. Patent 5,614,217 to Chiprich et al (hereinafter Chiprich et al). The rejection is traversed.

Ohki et al does not render claim 1, for example, unpatentable. Claim 1 is to an aerosolization system comprising, inter alia, an aerosolization device comprising a chamber adapted to receive a receptacle containing a pharmaceutical formulation, the receptacle comprising a wall having a weakened portion that opens when a force is applied. Ohki et al, in contrast, utilizes a conventional capsule and creates an opening therein by advancing perforating pins (21, 23) into the capsule (see Figures 7 and 8). Ohki et al does not disclose or suggest a capsule comprising a wall having a weakened portion that opens when a force is applied, as recited in claim 1. Therefore, Ohki et al does not alone render claim 1 unpatentable.

Furthermore, it would not have been obvious to one having ordinary skill in the art to modify Ohki et al in a manner that would arrive at the invention set forth in Applicant's claim 1. The Examiner posits that it would have been obvious to so modify Ohki et al in view of the teachings of Chiprich et al. Applicant disagrees.

Chiprich et al teaches a gelatin capsule that is breakable with manual pressure. Chiprich et al's capsule are for holding liquid filling material (see column 1 lines 42-43).

One of ordinary skill in the art would not have found it obvious to combine the teachings of Chiprich et al with Ohki et al. First, there is no motivation or suggestion to do so.

Ohki et al discloses a dry powder aerosolization apparatus. There is no reason why one of ordinary skill in the art would be motivated to make the modification suggested by the Examiner.

Furthermore, one of ordinary skill in the art would, in actuality, be taught away from making the proposed modification. Ohki et al specifically discloses a capsule hole forming technique where holes are formed on opposite ends of the capsule so that aerosolization air may flow through the capsule. The openings formed by the Ohki et al puncturing mechanism align with air flow passageways in the Ohki et al device (see elements 14 and 15). One of ordinary skill in the art would recognize that forming openings into a capsule using a brittle fracture technique, such as the one taught by Chiprich et al, would not result in the creation of consistent openings into the capsule and openings would often be created that did not align properly with the airflow passageways of the Ohki et al device. Accordingly, one of ordinary skill in the art would be taught away from performing the modification proposed by the Examiner, i.e. the elimination of the described perforation mechanism and use instead of a manually openable capsule. Since one of ordinary skill in the art would be taught away from making the proposed modification, one of ordinary skill in the art would not have found it obvious to modify Ohki et al as suggested by the Examiner.

In addition, to make the modification proposed by the Examiner would destroy the teachings of Ohki et al. Ohki et al's described invention is focused in large part on the perforation mechanism. According to the Examiner, one of ordinary skill in the art would be motivated to ignore the lengthy and detailed discussion of Ohki et al concerning these perforations and to make a modified device that fails to incorporate the express teachings of the Ohki et al references. Such a position is untenable, and one of ordinary skill in the art would not find it obvious to destroy the teachings of Ohki et al, particularly absent a suggestion to do so.

For at least these reasons, the Examiner is requested to reconsider the teachings of the references and to withdraw the rejection of present claim 1.

Claims 2-13 and 36 depend from claim 1 and are allowable over the combination of references for at least the same reason as the claim from which they depend. In addition, claims 2-13 recite further limitations that distinguish the applied references. For example, claim 4 recites a "force applying member" which is not disclosed in Ohki et al or Chiprich et al. Claim 12 recites that the pharmaceutical formulation has a mass median diameter less than 10  $\mu\text{m}$ . Ohki et al and Chiprich et al do not disclose or suggest such a pharmaceutical formulation.

Independent claim 14 is also not rendered unpatentable by Ohki et al and Chiprich et al. Claim 14 recites a method of aerosolizing a pharmaceutical formulation, the method comprising, inter alia, providing an aerosolization device comprising a chamber and providing a receptacle containing a pharmaceutical formulation, the receptacle comprising a wall having a weakened portion that opens when a force is applied. Ohki et al and Chiprich et al do not disclose or suggest such a device and receptacle, as discussed above. Therefore, claim 14 and its dependent claims 15-26 and 37 are not rendered unpatentable by Ohki et al and Chiprich et al.

In addition, claim 27 is not rendered unpatentable by Ohki et al and Chiprich et al. Claim 27 is to a receptacle for use in an aerosolization device comprising a chamber adapted to receive the receptacle, the receptacle comprising, inter alia, a wall having a weakened portion that opens when a force is applied and an aerosolizable pharmaceutical formulation within the wall. Ohki et al and Chiprich et al do not disclose or suggest an aerosolizable pharmaceutical formulation in a receptacle having a wall with a weakened portion, as discussed above. Thus, claim 27 and claims 28-35 depending therefrom are not rendered unpatentable by Ohki et al and Chiprich et al.

**Conclusion**

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

NEKTAR THERAPEUTICS  
(formerly INHALE THERAPEUTIC  
SYSTEMS)

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By: 

Guy V. Tucker  
Reg. No. 45,302

Please send all correspondence to:  
Guy Tucker  
Nektar Therapeutics  
(formerly Inhale Therapeutic Systems, Inc.)  
150 Industrial Road  
San Carlos, CA 94070  
Phone: (650) 620-5501  
Fax: (650) 631-3125